INSTRUMENT PROCESSING FROM PREP/PACKAGING TO STORAGE

January 2016

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Objectives

- Describe instrument processing between the prep and packaging phase to the storage area
- Explain sterilization process monitoring
- List load-release criteria and explain the steps involved
- Identify requirements to complete the Load Release Document

New AF Dental Guidelines

- The *USAF Dental Guidelines for Infection Prevention and Control in Dentistry* is currently under revision. New initiatives emphasized in this presentation will be included in the revision and are highlighted in green text.
- These new initiatives, which were initially briefed during the 2016 Organization for Safety Asepsis and Prevention (OSAP) AF breakout in January are designed to heighten patient safety
- Please begin implementing these initiatives to aid in our collective efforts toward:
  - the goal of zero patient harm
  - becoming a highly reliable organization

Before Prep/Packaging

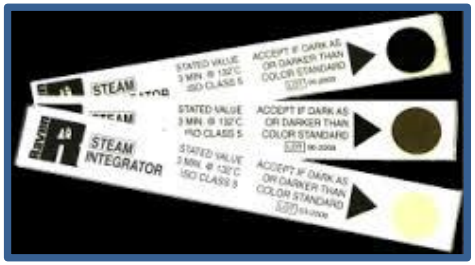
- After cleaning and decontamination (washer disinfector), instruments are safe for handling
  - In cases where instruments have been manually cleaned or put through the ultrasonic, heavy-duty gloves must be worn
- Inspect instruments for damage and remaining debris
  - Consider magnification
  - Replace/re-wash damaged or unclean instruments

Instrument Prep/Packaging

- Workflow is important
  - Make sure flow goes in one direction
  - Ensure packaging area is dedicated to clean instruments only
  - Physical separation of functional work areas is ideal
    - When physical separation is not possible, use other means to clearly separate work areas (signs/tape or physical barriers, e.g. tables)

Instrument Prep/Packaging

- Internal Chemical Indicators (CIs)
  - Designed to respond to one or more critical variables (Time, Temperature, Pressure) at a stated value
  - Single-variable (Class 3): reacts to one of the three critical variables
  - Multi-variable (Class 4): reacts to two or more critical variables
  - **Integrator (Class 5): reacts to all critical variables**
    - Stated values are equal to or greater than value requirements for Biological Indicators (BIs)
  - Emulator (Class 6): reacts to all critical variables of specified sterilization cycles

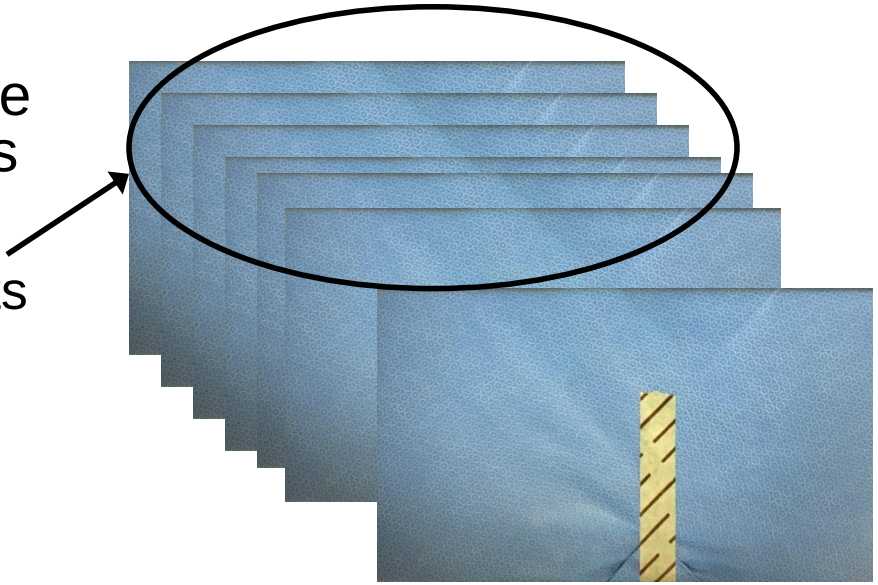


Instrument Prep/Packaging

- Integrators (Class 5 CI)
  - New initiative: Integrator (Class 5 CI) in every pack/kit
    - Including packs with built-in CI
    - Used for steam sterilization only
    - For instrument trays with multiple levels, place an integrator on each level

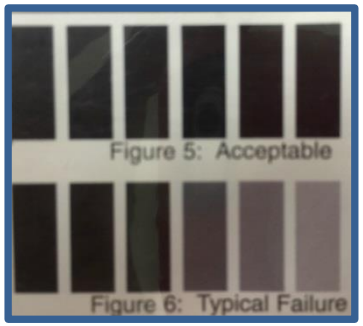
Instrument Prep/Packaging

- External Chemical Indicators (CI)
  - New initiative: Ensure CI tape is visible on all sides of wrapped packages
  - Placed on every package when internal indicator is not visible
    - Easier to determine if kits have been processed



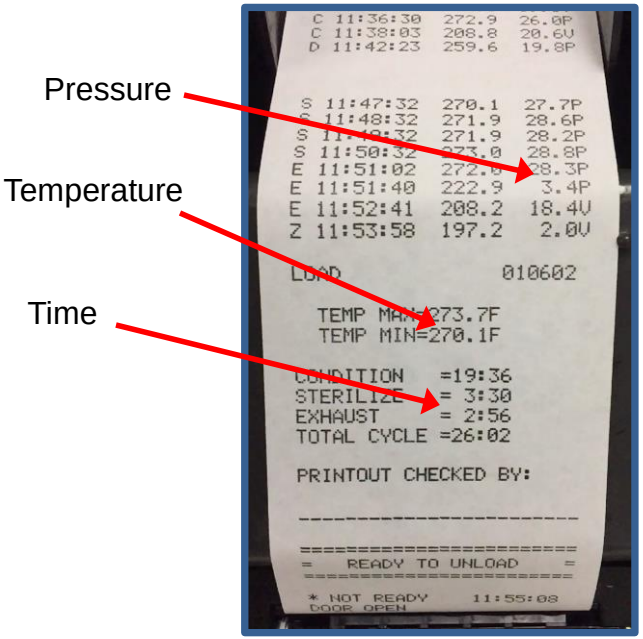
Routine Sterilizer Monitoring

- Physical monitoring
- External and internal chemical indicator (CI) monitoring
- Biological indicator (BI) monitoring
- Bowie-Dick testing



Physical Monitoring

- Provides real time assessment of Time, Temperature and Pressure (TTP) for each cycle
  - Print-out indicates cycle type and verifies proper sterilizer function
  - At cycle end, **BEFORE ITEMS ARE REMOVED FROM STERILIZER:**
    - 1. Review print-out to ensure correct TTP were achieved
    - 2. Initial print-out
- Detects sterilizer malfunctions
- Creates permanent record



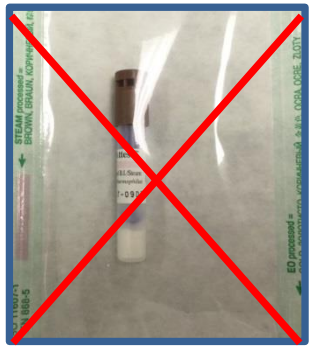
Internal & External CIs

- Chemical Indicators (CIs) help detect sterilization process failures immediately
  - Incorrect packaging/loading
  - Sterilizer malfunctions
  - Only one part of quality assurance
    - Must be used in conjunction with physical monitoring and BI monitoring

CI's alone DO NOT verify sterility

Biological Indicators (BI)

- Biological indicator MUST be within a Process Challenge Device (PCD)/ challenge “test pack”
  - DO NOT use the BI without PCD
- Run at least weekly, but preferably daily
- Must be included in all loads containing implants

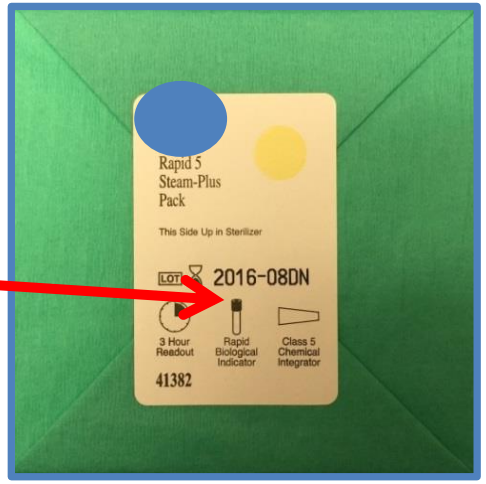


Process Challenge Device (PCD)

- Also known as challenge “test pack”
- Floor size sterilizers (larger than 2 cubic feet):
  - PCDs can be user-assembled or commercially-purchased
  - User-assembled PCDs – a 16 surgical towel method (directions are in AAMI ST79 10.7)
- Table top sterilizers:
  - Commercial PCDs may be difficult to find
  - User-assembled PCDs – a pack/kit that is routinely processed (use the pack/kit that is most difficult to sterilize)

Process Challenge Device (PCD)

- Types of PCDs:
  - BI alone
  - **BI and Integrator (Class 5 CI)***
  - **Integrator (Class 5 CI)***
  - Emulator (Class 6 CI)



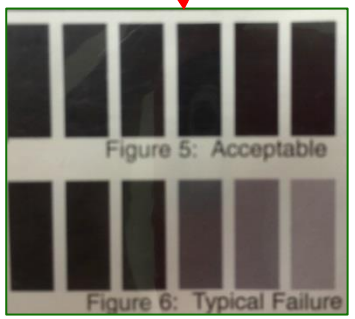
- New initiative: PCD/challenge test pack with an integrator (Class 5 CI) in every load
- BIs are not required for each load unless your local policy states otherwise.

* Used in AFDS clinics

Bowie-Dick / Daily Air Removal Test (DART®)

- For pre-vacuum steam sterilizers only
- Must be performed DAILY
- Perform test in an empty chamber
- DO NOT perform test in a cold sterilizer
  - Warm-up cycle must be completed before test
- If Bowie-Dick/DART® fails, refer to manufacturer's IFU

Acceptable Results



Typical Failure

Leak Test Cycle

- Some pre-vacuum sterilizers require running a Leak test cycle in addition to the Bowie-Dick/DART® test
  - Perform Leak test cycle daily or weekly IAW manufacturer's IFU
- This is a different air removal test that verifies the mechanics needed for the Bowie-Dick/DART® are working properly
  - If the Leak test cycle is not working properly:
    - There is a possibility of insufficient vacuum & inadequate sterilization
    - Bowie-Dick/DART® test may still pass (false pass)

Loading the Sterilizer

- Load items with similar cycle variables together
  - Check instrument IFU for cycle variable requirements
- DO NOT overload
  - To ensure adequate air removal (vacuum)
  - To ensure adequate steam penetration into each pack/kit

Loading the Sterilizer

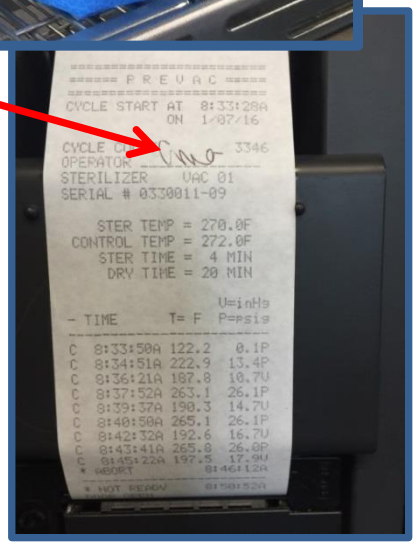
- Instrument Kits
  - Ideally, perforated kits should lie flat in the sterilizer, allowing maximum drainage of condensation
  - It is also acceptable to load kits on their sides
  - DO NOT stack peel packs or wrapped kits
  - Aesculaps can be stacked (no higher than 18”)
  - Orient all in same direction & ensure adequate space between each kit
    - Allows even distribution of steam with least resistance

Loading the Sterilizer

- Packs/pouches
  - Stand on edge
  - Paper side of one pouch should face the plastic side of adjacent pouch
  - Load lighter items on top shelf

Loading the Sterilizer

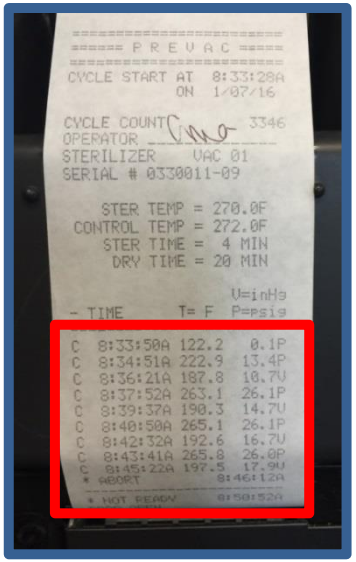
- Load wrapped packages so external indicator tape is easily visible
- Select the correct cycle IAW instrument manufacturer IFU
- Wait for machine to start and initial print-out
  - DO NOT select a cycle and then leave before the cycle actually starts



Routine Load Release

Verify Time/Temperature/Pressure (TTP)

1. Examine Print-out for:
   - Correct cycle
   - Minimum required Time
   - Minimum required Temperature
   - Pressure (value at the minimum required Temperature)
2. Initial Print-out
3. New initiative: AFDS Sterilizer Load Release Document completed for each load
   - Document cycle type, minimum Time, minimum Temperature, Pressure etc.
   - Affix load sticker and Integrator (Class 5 CI)



Never reached min temp

Routine Load Release

Verify External & Internal CIs

1. Visually examine external CI tape on packs/kits
   - Easier when wrapped kits have standard wrapping methods and are oriented so tape is easily viewed
2. Visually examine integrators (Class 5 CIs) in kits/packs
3. Remove integrator from PCD and affix to Load Release Document

Attachment 1

AFDS STERILIZER LOAD-RELEASE DOCUMENT

Date: _____ Sterilizer #: _____ Load #: _____ Load Sticker: (attach here)

Load Requirements / Cycle Times			
Cycle #/Type:	Minimum ***TEMPERATURE*** Required (°F/°C):	Minimum ***TIME*** Required (minutes):	
Cycle Start Time:	_____ Technician Name (*Stamp or Print*)	_____ Technician Initials	
Cycle End Time:	_____ Technician Name (*Stamp or Print*)	_____ Technician Initials	

Physical Monitors (*Time, Temperature and Pressure*)	
Was Minimum Required Temperature Reached? YES NO (circle one)	Time Minimum Temperature was Reached: :
Minimum Required Pressure (psi):	Time Minimum Temperature Ended: :
Total Time at Minimum Temperature:	

Chemical Indicator Monitors	
Bowie Dick (DART) Test: PASS FAIL (circle one)	
Did ***External*** Indicators (Tape) Change? (Yes/N):	Did ***Internal*** Indicators Change? (Y/N):
Integrator within a Process Challenge Device (PCD) – Each Load Must Contain an Integrator (Class 5) CI within a PCD – *- Affix Class 5 Integrator Here -*	

Biological Monitors					
A Biological Indicator (BI) within a PCD must be accomplished daily or weekly IAW local policy *** BI within a PCD must be accomplished when load contains an implant ***					
BI accomplished:		this load	or	Date/Time/Load accomplished:	
BI Test This Load	Test	Negative Changed color indicating spores were killed effectively	(circle one)	Positive Did not change color indicating spores were not killed	
	Control	Negative Changed color indicating spores were killed effectively	(circle one)	Positive Did not change color indicating spores were not killed	

Storage

- Sterile instruments should be stored in a manner in which sterility is maintained
  - Rotate stock
    - First in first out
  - DO NOT stack
    - Align instrument kits in a fashion resembling books on a shelf or similar to dominos
  - DO NOT place packs under heavy items that can crush or damage packs

Storage

- Instruments should be stored so that the External CI tape is visible
- Event-related sterility
  - Items do not expire based on time
  - Torn, damaged or wet packs/kits will compromise the package integrity and result in non sterile items
  - Yellowing packs is also a sign of compromise to package integrity

Summary / Takeaways

- **No single monitoring method is sufficient to assure sterility!**
- **Verification of all monitoring methods is essential!**
  - Physical (TTP)
  - Chemical (External/Internal CIs & Bowie-Dick/DART®)
  - Biological
- Have load release criteria readily available
- AFDS Initiatives (pending release of revised AFI 47-101 and the USAF Guidelines for Infection Prevention and Control in Dentistry)
  - Integrator (Class 5 CI) in every pack/kit
  - Ensure CI tape is visible on all sides of wrapped packages
  - PCD/challenge test pack with an integrator (Class 5 CI) in every load
  - AFDS Sterilizer Load Release Document completed for each load (this will be piloted at a few DTFs before mass release)

References

- Association for the Advancement of Medical Instrumentation, American National Standards Institute. Comprehensive guide to steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST79:2010/A1:2010/A2:2011/A3:2012/A4:2013. Arlington, VA: Association for the Advancement of Medical Instrumentation, Consolidated Text 2014
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- Cuny E.The use of a process challenge device in dental office gravity displacement tabletop sterilizers. American Journal of Infection Control 2015; 43:1131-1133
- USAF Guidelines for Infection Control in Dentistry.